UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/150,813	09/11/1998	DAVID J. GRAINGER	295.027US1	6933

21186 7590 09/12/2002

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
MURPHY, JOSEPH F	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 09/12/2002

34

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/150,813	Applicant(s) GRAINGER ET AL.	
	Examiner Joseph F Murphy	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *63-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *63-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *26* .
4) ☒ Interview Summary (PTO-413) Paper No(s). *33* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Formal Matters

The finality of the last Office action is withdrawn, and new grounds of rejection are set forth below. Claims 17, 20, 22, 34, 41-44 and 52-62 were cancelled, and new claims 63-74 were added in Paper No. 32, 4/11/2002. Claims 63-74 are pending and under consideration.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 63, 65, 67, 71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting chemokine induced THP-1 migration by administration of SEQ ID NO: 1, 7, 14 and CRD-CLDPKQKWIQC, does not reasonably provide enablement for a method of preventing or inhibiting an indication of a chemokine induced activity, or an indication associated with a chemokine induced activity by administration of peptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

There is insufficient guidance provided in the instant specification as to how one of ordinary skill in the art would practice a method of preventing or inhibiting an indication of a chemokine induced activity, or an indication associated with a chemokine induced activity. In the specification, indications associated with a chemokine induced activity include, *inter alia*, multiple sclerosis (Specification at 47). See In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The Wands Court set forth eight factors to consider in the determination of whether a disclosure does not satisfy the enablement requirement and would require undue experimentation. The relevant factors in the instant case are set forth below:

(1) the nature of the invention - is a method of preventing or inhibiting an indication of a chemokine induced activity, or an indication associated with a chemokine induced activity, which encompasses multiple sclerosis.

(2) the state of the prior art - the prior art teaches that the cause of MS is unknown (Merck Manual at 1474) thus methods of prevention are not known in the art. The prior art teaches methods of treatment of MS are difficult to evaluate, due to spontaneous remissions and fluctuating symptoms (Id. at 1476), but that corticosteroids and interferon-β, and symptomatic therapies are indicated (Id. at 1476). Methods of preventing or inhibiting an indication of a chemokine induced activity, or an indication associated with a chemokine induced activity with the claimed peptides are not art recognized. The Merck Manual shows the art does not recognize the nexus between the claimed method of administration of peptides and preventing or inhibiting multiple sclerosis.

(3) the level of one of ordinary skill - A medical professional would be considered one of ordinary skill in this art.

(4) the level of predictability in the art - the art is such that absent *in vivo* clinical data it would require undue experimentation to practice this method of preventing or inhibiting an indication of a chemokine induced activity, or an indication associated with a chemokine induced activity, which encompasses multiple sclerosis.

(5) the amount of direction provided by the inventor - the specification has provided insufficient guidance to the skilled artisan to practice a method of preventing or inhibiting an indication of a chemokine induced activity, or an indication associated with a chemokine induced activity, which encompasses multiple sclerosis. The Specification has not provided the nexus between the etiology or the treatment of multiple sclerosis and the claimed method of administration of peptides. The specification does not set forth treatment regimens, including dosages, dosage forms, preferred routes of administration or dosing schedules for the disclosed peptides.

(6) the existence of working examples - there are no working examples provided in the specification for a method of preventing or inhibiting an indication of a chemokine induced activity, or an indication associated with a chemokine induced activity, which encompasses multiple sclerosis by administration of peptides.

(7) the quantity of experimentation needed to make or use the invention based on the content of the disclosure - the quantity of experimentation would be undue because the skilled artisan would need to establish the nexus between the claimed method of administration of peptides and preventing or inhibiting multiple sclerosis. Then the skilled artisan would need to establish treatment protocols using the disclosed peptides, which would entail determining preferred routes of administration of the peptides, dosage forms, dosages, and dosing timetables.

Therefore, given the disclosure of The Merck Manual, representative as it is of the state of the art, it would require undue experimentation for one of skill in the art to practice a method of preventing or inhibiting an indication of a chemokine induced activity, or an indication

associated with a chemokine induced activity, which encompasses multiple sclerosis, by administration of the disclosed peptides.

Claims 64, 66, 68, 69, 70, 72, 73, 74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting chemokine induced THP-1 migration by administration of SEQ ID NO: 1, 7, 14 and CRD-CLDPKQKWIQC, does not reasonably provide enablement for a method of preventing or inhibiting an indication associated with hematopoietic cell recruitment, a method to enhance or increase hematopoietic cell-associated activity at a tumor site, or a method to modulate the chemokine induced activity of hematopoietic cells at a preselected physiological site, which encompasses myeloproliferative disorders (Specification at 23, lines 19-24), by the administration of peptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

There is insufficient guidance provided in the instant specification as to how one of ordinary skill in the art would practice a method of preventing or inhibiting an indication associated with hematopoietic cell recruitment, a method to enhance or increase hematopoietic cell-associated activity at a tumor site, or a method to modulate the chemokine induced activity of hematopoietic cells at a preselected physiological site, which encompasses myeloproliferative disorders, by the administration of peptides. See In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The Wands Court set forth eight factors to consider in

the determination of whether a disclosure does not satisfy the enablement requirement and would require undue experimentation. The relevant factors in the instant case are set forth below:

(1) the nature of the invention - is a method of preventing or inhibiting an indication associated with hematopoietic cell recruitment, a method to enhance or increase hematopoietic cell-associated activity at a tumor site, or a method to modulate the chemokine induced activity of hematopoietic cells at a preselected physiological site, which encompasses myeloproliferative disorders, by the administration of peptides.

(2) the state of the prior art - the prior art teaches that the cause of, e.g. myelofibrosis, is unknown (Merck Manual at 900), thus there are no art recognized methods to prevent this myeloproliferative disorder is known. Additionally, the Merck Manual (Id. at 901) teaches that there is no therapy to reverse or control the underlying pathologic process. Thus, methods of preventing or inhibiting an indication associated with hematopoietic cell recruitment, a method to enhance or increase hematopoietic cell-associated activity at a tumor site, or a method to modulate the chemokine induced activity of hematopoietic cells at a preselected physiological site, which encompasses myeloproliferative disorders, by the administration of peptides is not art recognized.

(3) the level of one of ordinary skill - A medical professional would be considered one of ordinary skill in this art.

(4) the level of predictability in the art - the art is such that absent *in vivo* clinical data it would require undue experimentation to practice this method of preventing or inhibiting an indication associated with hematopoietic cell recruitment, a method to enhance or increase hematopoietic cell-associated activity at a tumor site, or a method to modulate the chemokine

induced activity of hematopoietic cells at a preselected physiological site, which encompasses myeloproliferative disorders, by the administration of peptides.

(5) the amount of direction provided by the inventor - the specification has provided insufficient guidance to practice a method of preventing or inhibiting an indication associated with hematopoietic cell recruitment, a method to enhance or increase hematopoietic cell-associated activity at a tumor site, or a method to modulate the chemokine induced activity of hematopoietic cells at a preselected physiological site, which encompasses myeloproliferative disorders, by the administration of the disclosed peptides. The Specification has not provided the nexus between the prevention or inhibition of a myeloproliferative disorder and the administration of the disclosed polypeptides. The specification does not set forth treatment regimens, including dosages, dosage forms, preferred routes of administration or dosing schedules for the disclosed polypeptides.

(6) the existence of working examples - there are no working examples provided in the specification for the method of preventing or inhibiting an indication associated with hematopoietic cell recruitment, a method to enhance or increase hematopoietic cell-associated activity at a tumor site, or a method to modulate the chemokine induced activity of hematopoietic cells at a preselected physiological site, which encompasses myeloproliferative disorders, by the administration of peptides.

(7) the quantity of experimentation needed to make or use the invention based on the content of the disclosure - the quantity of experimentation would be undue because the skilled artisan would need to establish the nexus between the prevention or inhibition of a myeloproliferative disorder and the administration of the disclosed polypeptides. Then the

skilled artisan would need to establish treatment protocols using the disclosed peptides, which would entail determining preferred routes of administration, dosage forms, dosages, and dosing timetables.

Therefore, given the disclosure of The Merck Manual, representative as it is of the state of the art, it would require undue experimentation for one of skill in the art to practice a method of preventing or inhibiting an indication associated with hematopoietic cell recruitment, a method to enhance or increase hematopoietic cell-associated activity at a tumor site, or a method to modulate the chemokine induced activity of hematopoietic cells at a preselected physiological site, by the administration of the disclosed peptides.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
September 10, 2002